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NASA Policy Directive

NPD 7170.1Effective Date: February 22, 2018
Expiration Date: February 22, 2023**COMPLIANCE IS MANDATORY FOR NASA EMPLOYEES**[Printable Format \(PDF\)](#)

Subject: Use of Human Research Genetic Testing

Responsible Office: Office of the Chief Health & Medical Officer

1. POLICY

a. This directive establishes policy, consistent with 42 U.S.C § 2000ff et seq and 5 U.S.C. § 552(a), as amended, for the use of human research genetic testing and analysis to ensure adequate ethical, privacy, and data use protections.

b. It is NASA's policy to:

(1) Voluntarily obtain and utilize human research genetic testing, data, and analysis for:

(a) Medical risk identification for space exploration.

(b) Development of engineering requirements for spacecraft.

(c) Mitigation of space hazards.

(d) Development and assessment of space health risk countermeasures.

(2) Utilize human research genetic testing, data, and analysis for:

(a) Occupational surveillance.

(b) Tailoring of individual countermeasures.

(c) Informing clinical care.

(3) Protect the privacy of genetic information, to the full extent of the law, including after death of the subject, to avoid unwarranted invasion of personal privacy of surviving family members.

(a) No whole genomic sequence data will be published or made public without written consent from the subject or their direct family members who may be impacted by the release of the data.

(b) Attributable or identifiable human research genetic data will not be publicly released without the prior approval of the individual research subject and other subjects whose anonymity might be affected by the release, as well as the appropriate NASA Institutional Review Board (IRB) or the Lifetime Surveillance of Astronaut Health.

(4) Require Principal Investigators to offer genetic counseling to research subjects, both before and after obtaining genetic information.

(5) Not utilize human research genetic information for employment decisions including, but not limited to, astronaut selection, training, and mission selection.

(6) Place research genetic information in a database separate from the employee's medical record. The genetic information database will be compliant with information technology security and privacy requirements of 5 U.S.C. § 552(a) protected records. Further, the records in this system, and associated analysis of the genetic information stored in the system, will not be accessible to NASA managers and supervisors who make employment decisions related to the individuals whose data is contained in the system.

(a) Individual subjects may request in writing that their human genetic research results be placed into their Electronic

Medical Record (EMR). Research results having direct implications for the clinical care of active astronauts will be included in the individual's EMR.

2. APPLICABILITY

a. This NPD is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This NPD applies to the Jet Propulsion Laboratory, a Federally Funded Research and Development Center, other contractors, recipients of grants, cooperative agreements, or other parties to agreements only to the extent specified or referenced in the appropriate contracts, grants, or agreements.

b. This policy applies to studies that include NASA employees and contractors as subjects or investigators; and/or have data collected as part of a NASA database.

c. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term "shall." The terms: "may" or "can" denote discretionary privilege or permission, "should" denotes a good practice and is recommended, but not required, "will" denotes expected outcome, and "are/is" denotes descriptive material.

d. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

3. AUTHORITY

The National Aeronautics and Space Act, as amended, 51 U.S.C. § 20113(a).

4. APPLICABLE DOCUMENTS AND FORMS

a. Privacy Act of 1974, as amended, 5 U.S.C. § 552(a).

b. Genetic Information Nondiscrimination Act of 2008, 42 U.S.C § 2000ff et seq.

c. NC 1000.12, Medical Policy Board and Aerospace Medicine Board.

5. RESPONSIBILITY

a. The Chief Health and Medical Officer (CHMO) is responsible for coordinating and monitoring this policy, to include conducting periodic reviews of its implementation, and receiving:

(1) Policy guidance and recommendations for changes to this NPD, and its corresponding NPR, from the Medical Policy Board, in accordance with NC 1000.12.

(2) From all NASA IRBs, in accordance with their respective established charters, annual reports of the number and type of human research genetic tests performed for research protocols, the number of human genetic incidental findings from research protocols, and the number of ethical and policy violations related to research protocols.

b. The Chief Information Officer is responsible to ensure privacy, system security, and authorization are appropriate for the storage, processing, and transmission of all data associated with human genetic testing.

c. The Program obtaining the human research genetic data is responsible for maintaining a genetic information database of their archived genetic testing data. All information technology systems used to store, process, or analyze genetic data will comply with information technology security and privacy information protection standards for systems containing 5 U.S.C. § 552(a) protected information.

6. DELEGATION OF AUTHORITY

None.

7. MEASUREMENT/VERIFICATION

a. The CHMO will annually measure compliance with this directive by:

(1) Monitoring the number and type of human research genetic tests performed for research protocols.

(2) Monitoring the number of human genetic incidental findings from research protocols.

(3) Monitoring the number of ethical and privacy violations.

8. CANCELLATION

None.

/s/ Robert Lightfoot
Acting Administrator

ATTACHMENT A: DEFINITIONS

Genetic Incidental Finding - a finding concerning a research subject having potential health impact discovered while conducting a research protocol beyond the original aims of the study.

Human Genetic Testing - an analysis of human Deoxyribonucleic acid (DNA), Ribonucleic acid (RNA), chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal and biochemical changes. These tests can include the following:

- a. Molecular genetic tests that study single genes or short lengths of DNA or RNA to identify variations or mutations,
- b. Chromosomal genetic tests that analyze the entire genome or whole chromosomes or long lengths of DNA or RNA,
- c. Biochemical genetic tests that study the amount or activity of proteins or metabolites and wherein any noted changes can indicate changes in (or characteristics of) DNA or RNA, and
- d. Microbiome testing from human subjects (gut, skin, etc.).

ATTACHMENT B: ACRONYMS

CHMO Chief Health and Medical Officer

DNA Deoxyribonucleic acid

EMR Electronic Medical Record

IRB Institutional Review Board

RNA Ribonucleic acid

ATTACHMENT C: REFERENCES

- C1. Prohibiting Discrimination in Federal Employment Based on Genetic Information, E. O. 13145 of Feb 8, 2000, 65 FR 6877.
- C2. Privacy Act - NASA Regulations, 14 CFR pt. 1212.
- C3. Genetic Information Nondiscrimination Act of 2008, 29 CFR pt. 1635.
- C4. U.S. Department of Health and Human Services, Basic HHS Policy for Protection of Human Research Subjects, 45 CFR 46, subpt. A.
- C5. NPD 1800.2, NASA Occupational Health Program.
- C6. NPD 7100.8, Protection of Human Research Subjects.
- C7. NPD 8900.1, Medical Operations Responsibilities in Support of Human Space Flight Programs.
- C8. NPR 1382.1, NASA Privacy Procedural Requirements.
- C9. NPR 1441.1, NASA Records Management Procedural Requirements.
- C10. NPR 1800.1, NASA Occupational Health Program Procedures.
- C11. NPR 8900.1, NASA Health and Medical Requirements for Human Space Exploration.
- C12. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Bethesda,

Md.]: The Commission, 1978.

(URL for Graphic)

None.

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